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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------|------------------|
| 10/089,177  | 03/27/2002  | Michel G Bergeron    | 1619.0090000/SRL/PJA | 9698             |
| 26111   | 7590        | 10/01/2004           | EXAMINER             |                  |
| STERNE, KESSLER, GOLDSTEIN & FOX PLLC<br>1100 NEW YORK AVENUE, N.W.<br>WASHINGTON, DC 20005 |             |                      | MYERS, CARLA J       |                  |
|   |             |                      | ART UNIT             | PAPER NUMBER     |
|   |             |                      | 1634                 |                  |
| DATE MAILED: 10/01/2004   |             |                      |                      |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/089,177

Applicant(s)

BERGERON ET AL.

Examiner

Carla Myers

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27, 29-37 and 39-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27, 29-37 and 39-48 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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**DETAILED ACTION**

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 6, 7, 12-21, 29, 30, and 44-48, drawn to methods for generating a repertory of nucleic acids and methods for generating probes and primers.

Group II, claim(s) 4, 5, 8-11, 22-27, 31-36 and 39-43, drawn to nucleic acids and banks of nucleic acids.

Group III, claim 37, drawn to peptides.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, the linking technical feature of a bank of nucleic acids does not constitute a contribution over the prior art. The claimed banks of nucleic acids (for example, claim 4) are so broad as to

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include the NCBI database of all nucleic acids. Thereby, banks of nucleic acids comprising a repertory of nucleic acids were known in the art at the time the invention was made and do not constitute a special technical feature. Further, nucleic acids for the universal detection of the microbial nucleic acids as set forth, for example, claims 8 and 9, were known in the art at the time the invention was made. In particular, Bergeron (U.S. Patent No., 6,001,564; cited in the IDS) discloses nucleic acids which detect *Enterococcus faecalis*, *Staphylococcus aureus*, *Staphylococcus saprophyticus*, *Enterococcus faecium*, and *Streptococcus pyogenes*. In view of the breadth of the claims, the nucleic acids of Bergeron read on the claimed nucleic acids. Thus, there is no special technical feature linking the recited groups, as would be necessary to fulfill the requirement for unity of invention.

Furthermore, the molecules of groups II and III do not share a corresponding structural property. The special technical feature of the nucleic acids of Group II is the identity of its monomers which are nucleotides and which determine its structure, properties and function. In contrast, the special technical feature of the proteins of Group III are its amino acid monomers, which determine its structure, properties and function which are arranged in a specific 3-dimensional structure. While nucleic acids bind to other nucleic acids and may be used in nucleic acid hybridization methods, the claimed peptides cannot be used in such methods. Further, while the claimed peptides bind to antibodies and other ligands and may be used in immunological detection assays, the claimed nucleic acids may not be used in such assays.

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Additionally, the methods of group I do not require the peptides of group III.

Moreover, the nucleic acids of group II may be used in methods materially distinct from the method of group I, such that the nucleic acids may be used to synthesize peptides or may be used for therapeutic purposes.

### **Sequence Election Requirement Applicable to All Groups**

3. In addition, each invention detailed above reads on patentably distinct inventions drawn to multiple SEQ ID Numbers.

It is noted that Applicants have presented the claims in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. The claims are improperly joined as the claimed methods and products require distinct nucleic acids and peptides. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.

Although the chemical compounds share a common structure in that they are nucleic acids (with respect to groups I and II) or are all peptide (with respect to group III), the compounds are not regarded as being of a similar nature because all of the alternatives do not share a common property or activity. Each of the nucleic acids is structurally and functionally distinct in that each nucleic acid consists of a unique nucleotide sequence, each binds to a distinct target nucleic acid, each has a distinct melting temperature and each encodes for a distinct peptide. Each of the peptides is structurally and functionally distinct in that each peptide consists of a unique amino acid

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sequence, has a distinct molecular weight, has a distinct isoelectric point and binds to a distinct ligand.

Given the differences in structure and function, the Markush group set forth in the claims is not considered to constitute a proper genus, and therefore is subject to a further restriction requirement. A sequence search and non-patent literature search of each of these sequences would not be co-extensive with one another. For example, a search for the *tuf/tus* primer of SEQ ID NO: 3 would not be co-extensive with a search for the *atpD* primer of SEQ ID NO: 562, and vice versa. Accordingly, a search of more than one of the sequences as claimed presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and the corresponding examination of more than one of the claimed sequences. Accordingly, in response to the restriction requirement, **Applicant must further elect a single nucleic acid or a single set of nucleic acids or primers.**

Note that this is a restriction requirement and should **not** be construed as an election of species.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

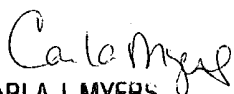
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)-272-0782.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Carla Myers  
September 29, 2004

  
CARLA J. MYERS  
PRIMARY EXAMINER